

(see 21 U.S.C. 355(j)(2)(B)(ii); 21 CFR 314.52(c)(6)).

Under the FDCA, an ANDA approval shall be made effective on the date certified by the ANDA applicant to be the date on which a patent expires (see 21 U.S.C. 355(j)(4)(B)(ii)), or immediately if certified by the ANDA applicant (1) that patent information has not been filed or that the patent has expired (see 21 U.S.C. 355(j)(4)(B)(i)); or (2) that the patent is invalid or will not be infringed, unless an action is brought within 45 days after the ANDA applicant gives notice to the patent holder under section 505(j)(2)(B)(i) of the FDCA (see 21 U.S.C. 355(j)(4)(B)(iii)).

The FDCA and implementing regulations provide no other mechanism by which to stay the effective date of an ANDA approval.

Under the FDCA, similar provisions apply to NADAs and ANADAs. Upon the approval of an NADA, FDA publishes required NADA patent information in its official publication, *FDA Approved Animal Drug Products* (referred to as the "Greek Book"). (See 21 U.S.C. 360b(b)(1)). ANADAs are subject to patent certification requirements (see 21 U.S.C. 360b(n)(1)(H)) and to approval effective dates (see 21 U.S.C. 360b(c)(2)(D)), similar to the ANDA provisions described above. The effective approval date of an ANADA, similar to an ANDA, is stayed only if an action is brought within 45 days after the ANADA applicant gives notice to the patent holder under 21 U.S.C. 360(n)(2)(B)(i), that the patent is not valid or will not be infringed. The FDCA provides no other mechanism by which to stay the effective date of an ANADA.

#### *Issues Upon Which Comments Are Sought*

Comments are requested regarding the effect of the URAA patent amendments upon the filing and approval of ANDAs and ANADAs. Specifically, comments are requested on the following questions:

1. Should FDA revised the patent term expiration dates currently listed in the Orange Book and Green Book for those patents entitled to a longer term under the URAA, because they are in force on June 8, 1995?

2. Should PTO, at the request of NDA or NADA holders, certify (or alternatively, verify) new patent expiration dates under the URAA for patents currently listed in the Orange Book and the Green Book?

3. Should NDA and NADA holders be required to submit to FDA revised patent expiration dates for those patents

currently listed in the Orange Book and Green Book that will have a longer term under URAA? If so, should such submissions be required to be made (1) by June 8, 1995, (2) only after PTO certifies or verifies the claimed patent term expiration date, or (3) within some other specified time period?

4. If revised patent term expiration dates are published in the Orange Book and the Green Book, then if PTO does not certify or verify the patent term expiration date identified by the NDA or NADA holder, what submission, if any, should FDA require to verify the date? Should FDA publish the revised patent term expiration date submitted by the NDA or NADA holder without verification?

5. If revised patent term expiration dates are published in the Orange Book and the Green Book, what revisions to patent certifications, if any should applicants with pending ANDAs or ANADAs be required to make? When should such revisions to patent certifications be made? What type of information related to substantial investment, if any, should ANDA and ANADA applicants be required to make with such revisions?

#### **II. The Effect of URAA on Existing Patent Term Extensions Under 35 U.S.C. 156**

Under 35 U.S.C. 156, patent term extensions are issued for eligible patents from the original expiration date of the patent. Since this provision was enacted in 1984, the PTO has issued 195 certificates of patent term extension in accordance with section 156. Under the URAA, patents in force on June 8, 1995, are entitled to a patent term of 17 years from grant or 20 years from filing, whichever is longer. The PTO estimates that 93 patents whose terms were extended under section 156 would be entitled to such longer patent term. The PTO has assumed, for the purpose of evaluating the number of extending patents that may be affected by the 20-year patent term, that a patent that would have expired (under the original 17-year patent term) before June 8, 1995, but has received a patent term extension for a period beyond June 8, 1995 (with the rights prescribed in 35 U.S.C. 156(b)), is a patent "in force" on June 8, 1995.

There are several ways to interpret the provision of the URAA that grants the longer of a 17 or 20-year patent term to patents in force on June 8, 1995, and that have been or will be extended under section 156. First, the extension already issued by the PTO could simply be added to the longer of the 17 or 20-year patent term. No action would be

required by the PTO. Second the extension already issued by the PTO could be interpreted to operate from "the original expiration date of the patent" (35 U.S.C. 156(a)), which could be interpreted as the expiration date of the 17-year patent term. Again, no action would be required by the PTO. A third interpretation could be that the appropriate extension under section 156 would be added to the longer of the 17 or 20-year patent term. This third interpretation would require the PTO to revise the extension granted in some cases as the 14-year limitation of a patent term counted from the date of market approval (35 U.S.C. 156(c)(3)) would be applicable to the extended patent term regardless of whether the original expiration date of the patent was 17 years from grant or 20 years from the filing date. The PTO seeks comments from the public on the appropriate course of action with respect to patents that have been or will be issued term extensions under section 156 of title 35, United States Code.

#### *Questions*

1. Should PTO take any action with respect to existing patent term extensions under section 156?

2. What approach should PTO take with respect to the calculation of new patent term extensions under section 156 where the patent is entitled to the longer of the 17 or 20-year patent term under the URAA?

Comments on any other issues relevant to the relationship between the URAA and the FDCA or existing patent term extensions under 35 U.S.C. 156 are also invited.

Dated: January 11, 1995.

**Michael K. Kirk,**

*Deputy Assistant Secretary of Commerce and Deputy Commissioner of Patents and Trademarks.*

[FR Doc. 95-1073 Filed 1-13-95; 8:45 am]

BILLING CODE 3510-16-M

---

#### **COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS**

##### **Adjustment of Import Limits for Certain Wool Textile Products Produced or Manufactured in the Slovak Republic; Correction**

January 10, 1995.

The letter to the Commissioner of Customs published in the **Federal Register** on December 16, 1994 (59 FR 65019) should be corrected as follows:

1. In column 2, paragraph 1, line 3, change "June 10, 1993" to read "June 7, 1994."

2. In column 2, paragraph 1, line 9, change "June 1, 1993 and extends through May 31, 1994" to read "June 1, 1994 and extends through May 31, 1995."

3. In column 3, paragraph 1, line 3, change "June 10, 1993" to read "June 7, 1994."

4. In the footnote, change "May 31, 1993" to read "May 31, 1994."

**Rita D. Hayes,**

*Chairman, Committee for the Implementation of Textile Agreements.*

[FR Doc. 95-1019 Filed 1-13-95; 8:45 am]

BILLING CODE 3510-DR-F

## DEPARTMENT OF DEFENSE

### Office of the Secretary

#### Marine Mammals

**AGENCY:** Advanced Research Projects Agency, DOD.

**ACTION:** Notice of public hearing on draft environmental impact statement.

**SUMMARY:** The Advanced Research Projects Agency (ARPA) in cooperation with the National Marine Fisheries Service (NMFS) will hold a public hearing on a Draft Environmental Impact Statement (DEIS) for the Kauai Acoustic Thermometry of Ocean Climate (ATOC) Project and its associated Marine Mammal Research Program.

**DATES:** The public hearing will take place on February 9, 1995 at 6:00 P.M., at the Kauai War Memorial Convention Hall, 4191 Hardy St., Lihue, Kauai, Hawaii.

**ADDRESSES:** To obtain a copy of the Draft EIS, contact Marilyn E. Cox, Campus Planning Office, 0006, 9500 Gilman Drive, University of California, San Diego, La Jolla, CA 92093. Telephone (619) 534-3860.

#### FOR FURTHER INFORMATION CONTACT:

All non-government organizations and scientists who wish to present prepared testimony should contact Mr. Eugene Nitta, Protected Species Program Coordinator, Pacific Ocean Area-NMFS at (808) (973)-2937 at least 48 hours before the hearing so that a general agenda can be prepared. A written copy of each testimony to be presented is requested on the day of the hearing. It is use slides or overheads only if absolutely necessary during presentations, and copies of any slides or overheads should be made available to Mr. Nitta on the day of the hearing.

Other persons interested in making a statement at this hearing should bring a written copy of the statement to the

hearing, and will be given an opportunity to make such statements following the prepared testimonies. Anyone who requires additional information or special accommodations to attend the public hearing should contact the person named above at least 7 days before the hearing. Comments on the Draft EIS will be accepted until February 20, 1995.

**SUPPLEMENTARY INFORMATION:** On April 15, 1994, notice was published in the Federal Register that the ARPA, in cooperation with the NMFS, intended to prepare an EIS, pursuant to the National Environmental Policy Act (NEPA), on an application for a scientific research permit to allow harassment of marine mammals and sea turtles by a low frequency sound source associated with the ATOC program in waters off Kauai, Hawaii, and to monitor the effects thereof. The ATOC project is a basin-scale-research effort to determine long-term ocean climate changes by using acoustic sound paths in the sea's deep "sound channel" to precisely measure average ocean temperatures. A two-year research program is proposed to be carried out to study any potential effects of the ATOC sound transmissions on marine mammals and sea turtles. Two sound sources are currently proposed; one off the north shore of Kauai, Hawaii (which is the subject of this Draft EIS) and the other offshore California near Point Sur (the subject of a separate draft EIS).

Dated: January 10, 1995.

**Patricia L. Toppings,**

*Alternate OSD Federal Register Liaison Officer, Department of Defense.*

[FR Doc. 95-995 Filed 1-13-95; 8:45 am]

BILLING CODE 5000-04-M

## Department of the Army

### Army Science Board; Notice of Closed Meeting

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (P.L. 92-462), announcement is made of the following Committee meeting:

*Name of Committee:* Army Science Board (ASB).

*Date of Meeting:* 31 January and 1 February 1995.

*Time of Meeting:* 0800-1630, 31 January 1995; 0800-1630, 1 February 1995.

*Place:* Arlington, VA.

*Agenda:* The Army Science Board 1995 Summer Study on "Army Support Operations Other Than War (OOTW)—Logistical Support" will meet for discussions focused on current doctrine, missions, functions, force structures and modules, and technologies. Briefings will be provided covering logistics lessons learned from

Somalia, Macedonia, and Haiti. Additionally, the Army's logistics initiatives will be briefed. This meeting will be closed to the public in accordance with Section 552b(c) of title 5, U.S.C., specifically subparagraph (1) thereof, and Title 5, U.S.C., Appendix 2, subsection 10(d). The classified and unclassified matters to be discussed are so inextricably intertwined so as to preclude opening any portion of the meeting. The ASB Administrative Officer, Sally Warner, may be contacted for further information at (703) 695-0781.

**Sally A. Warner,**

*Administrative Officer, Army Science Board.*

[FR Doc. 95-1110 Filed 1-13-95; 8:45 am]

BILLING CODE 3710-08-M

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

[Docket No. RP93-99-005]

### Colorado Interstate Gas Co.; Notice of Tariff Compliance Filing

January 10, 1994.

Take notice that on January 4, 1995, Colorado Interstate Gas Company (CIG), tendered for filing as part of its FERC Gas Tariff, First Revised Volume No. 1, revised tariff sheets, and FERC Gas Tariff, Original Volume No. 2. CIG states that the new tariff sheets were filed to comply with the letter order issued November 10, 1994, in Docket No. RP93-99-000, et al. ("Order").

Accordingly, CIG submitted for filing the following tariff sheets:

First Revised Volume No. 1

Substitute Third Revised Sheet No. 7

Substitute Third Revised Sheet No. 8

Substitute Third Revised Sheet No. 9

Second Substitute Third Revised Sheet No. 9

Substitute Fourth Revised Sheet No. 10

Second Substitute Fourth Revised Sheet No. 10

Substitute Third Revised Sheet No. 12

Substitute Second Revised Sheet No. 358

Original Volume No. 2

Substitute Eleventh Revised Sheet No. 463

The Order approved the Stipulation and Agreement (Stipulation) filed by CIG on August 16, 1994. The Stipulation establishes rates for CIG's post-restructuring period beginning on October 1, 1993 and the tariff sheets are being filed to implement these rates.

CIG states that a copy of this filing was served upon all parties in this proceeding.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with Section 385.211 of the